SAB MEETING

October 1-2-3, 2002

The Jefferson Hotel
101 W. Franklin Street
Richmond, VA

Phone: 804-788-8000
Fax: 804-225-0334

PM3003571934

Source: https://www.industrydocuments.ucsf.edu/docs/qfnj0001

SAB Meeting – Day 1
Tuesday, October 1, 2002
Flemish Room

Topic/Presenter(s)	Time
BREAKFAST *Harrison Room*	7:45 a.m. – 8:30 a.m.

EHCSS – JLI

Presentation of scientific framework for support of an exposure claim according to IOM Principle #4 for JLI non-menthol

➢ Welcome & Introductions George Patskan/Richard Solana	8:30 a.m. – 9:00 a.m.
➢ Overview of IOM principles with a focus on #4 George Patskan	9:00 a.m. – 9:30 a.m.
➢ Overview of EHCSS JLI Product Sue Wrenn	9:30 a.m. – 10:00 a.m.
BREAK	10:00 a.m. – 10:15 a.m.
➢ Introduction to Clinical Studies H. Roethig	10:15 a.m. – 10:45 a.m.
➢ Biomarkers of Exposure (Selection, Methods and Validation, Acceptance) Robin Kinser	10:45 a.m. – 11:45 a.m.
LUNCH/BREAK *(Harrison Room)*	11:45 a.m. – 12:45 p.m.
➢ Clinical Exposure Evaluation (Standard Protocol and Learnings from Accord E4 Study) Hans Roethig	12:45 p.m. – 1:45 p.m.
➢ Accord JLI short term exposure study (Results/Comparison to E4 data) Qiwei Liang	1:45 p.m. – 2:45 p.m.

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SAB Meeting – Day 1 - continued
Tuesday, October 1, 2002
Flemish Room

BREAK 2:45 p.m. – 3:00 p.m.

- Accord studies running and data to be expected for comparison with Accord JLI short term exposure study and support of reduced exposure claims

  - Long-term Exposure Study 3:00 p.m. – 3:30 p.m.
    Bettie Nelson

  - Menthol Study 3:30 p.m. – 4:00 p.m.
    Jan Oey

SAB Closed Session 4:00 p.m. – 5:00 p.m.

Dinner Plans – Meet in hotel lobby **6:15 p.m.**
Restaurant – Amici Restaurant **(depart at 6:30 p.m.)**
3343 W. Cary Street
(Shuttle arranged)

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SAB Meeting – Day 2
Wednesday, October 2, 2002
Flemish Room

BREAKFAST *Harrison Room*	8:15 a.m. – 9:00 a.m.
➢ Review of Non-clinical Data E. Roemer/P. Vanscheeuwijck	9:00 a.m. – 11:15 a.m.
BREAK *to be taken during above presentation*	
➢ Analysis of data relative to the anticipated measurable reduction in morbidity and/or morality described in IOM Principle #4	
- CVD (e.g. CO) Klaus von Holt	11:15 a.m. – 12:15 p.m.
LUNCH/BREAK *(Harrison Room)*	12:15 p.m. – 1:15 p.m.
- Cancer (e.g. carcinogens, genotox) Anthony Tricker	1:15 p.m. – 2:15 p.m.
- COPD (e.g. inflammation, cytotox) Willie McKinney	2:15 p.m. – 3:15 p.m.
BREAK	3:15 p.m. – 3:30 p.m.
➢ Overall Conclusions George Patskan/Robert Elves	3:30 p.m. – 4:00 p.m.
SAB Closed Session	4:00 p.m. – 5:15 p.m.

Dinner Plans – LeMaire Restaurant (in Hotel Jefferson)
Cocktails: 6:30 p.m.
Dinner: 7:00 p.m.

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SAB Meeting – Day 3
Thursday, October 3, 2002
Flemish Room

BREAKFAST *Harrison Room*	8:15 a.m. – 9:00 a.m.
➢ Philip Morris Brands Study Ewald Roemer	9:00 a.m. – 9:45 a.m.
➢ A Quantitative Approach for Combining Clinical and Non-clinical Data George Patskan	9:45 a.m. – 10:15 a.m
BREAK	10:15 a.m. – 10:30 a.m.
➢ TES Pilot Study Results Mohamadi Sarkar	10:30 a.m. – 11:30 a.m.
➢ TES Protocol Hans Roethig	11:30 a.m. – 12:15 p.m.
LUNCH/BREAK *(Harrison Room)*	12:15 a.m. – 1:00 p.m.
SAB Closed Session	1:00 p.m. – 2:00 p.m.
Wrap-up	2:00 p.m. – 3:00 p.m.

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